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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,207

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EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

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DELIVERY MODE

06/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,207	Applicant(s) NEWGARD ET AL.	
	Examiner AMY E. JUEDES	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3-12, 15-16, 19-20, 23-24, 32-35, 43, 47-48, 52-54, 56, 59, 61, 64, 66-68, 71, 74, 76-78, 81, and 84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3-12,15,16,19,20,23,24,32-35,43,47,48,52-54,56,59,61,64,66-68,71,74,76-78,81 and 84.

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DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1 link(s) inventions 1-7. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1, claims 3-4, 10-11, drawn to a method of treating diabetes comprising administering a compound that enhances ketolytic activity, wherein the compound is a polypeptide/antibody.

Group 2, claims 3-4, 12, 35, 43, drawn to a method of treating diabetes and a method of reducing ketone levels comprising administering a compound that enhances ketolytic activity, wherein the compound is a nucleic acid.

Group 3, claims 5-6, 10-11, drawn to a method of treating diabetes comprising administering a compound that reduces ketogenic activity, wherein the compound is a polypeptide/antibody.

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Group 4, claims 5-6, 9, drawn to a method of treating diabetes comprising administering a compound that reduces ketogenic activity, wherein the compound is a succinate ester or precursor.

Group 5, claims 5-6, 12, drawn to a method of treating diabetes comprising administering a compound that reduces ketogenic activity, wherein the compound is a nucleic acid.

Group 6, claims 7-8, 10-11, drawn to a method of treating diabetes comprising administering a compound that enhances hepatic fatty acid oxidation, wherein the compound is a polypeptide/antibody.

Group 7, claims 7-8, 12, 47-48, drawn to a method of treating diabetes and a method of reducing ketone levels comprising administering a compound that enhances hepatic fatty acid oxidation, wherein the compound is a nucleic acid.

Claims 15 and 32 link(s) inventions 8-9. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 15 and 32. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 8-9, claim 16, drawn to delivery vector comprising a nucleic acid molecule encoding a ketolytic enzyme, wherein groups 8 and 9 correspond to nucleic acids encoding SCOT and alpha-ketoacid dehydrogenase, respectively.

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Claims 19 and 33 link(s) inventions 10-16. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 19 and 33. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 10-16, claim 20, drawn to delivery vector comprising a nucleic acid molecule encoding a an enzyme that mediates fatty acid oxidation, wherein groups 10-16 correspond to nucleic acids encoding malonyl CoA decarboxylase, carnitinepalmitoyltransferase, carnitine acyltranslocase, acyl-CoA dehydrogenase, enoyl-CoA hydratase, 3-L-hydroxyacyl-CoA dehydrogenase, and beta-ketoacyl-CoA thiolase, respectively.

Claims 23 and 34 link(s) inventions 17-20. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 23 and 34. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

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restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 17-20, claim 24, drawn to an inhibitor oligonucleotide that targets a ketogenic enzyme, wherein groups 17-20 correspond to the enzymes beta-hydroxybutyrate dehydrogenase, mitochondrial HMG-CoA synthase, acetoacetyl-CoA thiolase, and HMG-CoA lyase, respectively.

Group 21, claims 52-53, drawn to a method of identifying a candidate compound comprising contacting a ketogenic enzyme with a compound.

Group 22, claims 54 and 59, drawn to a method of identifying a candidate compound comprising contacting a cell with a compound or administering a compound, and detecting ketone levels.

Group 23, claims 56 and 61, drawn to a method of identifying a candidate compound comprising contacting a cell with a compound or administering a compound, and detecting ketogenic enzyme concentration or activity.

Group 24, claim 64, drawn to a method of identifying a candidate compound comprising administering a compound to a transgenic non-human mammal comprising a nucleic acid encoding a ketogenic enzyme, and detecting the level of insulin resistance.

Group 25, claim 66-67, drawn to a method of identifying a candidate compound comprising contacting an enzyme that mediates fatty acid oxidation with a compound.

Group 26, claim 68 and 71, drawn to a method of identifying a candidate compound comprising contacting a cell with a compound or administering a compound and detecting the concentration or enzymatic activity of an enzyme that mediates fatty acid oxidation.

Group 27, claim 74, drawn to a method of identifying a candidate compound comprising administering a compound to a transgenic non-human mammal comprising a nucleic acid

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encoding an enzyme that mediates fatty acid oxidation, and detecting the level of insulin resistance.

Group 28, claims 76-77, drawn to a method of identifying a candidate compound comprising contacting a ketolytic enzyme with a compound.

Group 29, claims 78 and 81, drawn to a method of identifying a candidate compound comprising contacting a cell with a compound or administering a compound, and detecting the concentration or activity of a ketolytic enzyme.

Group 30, claim 84, drawn to a method of identifying a candidate compound comprising administering a compound to a transgenic non-human mammal comprising a nucleic acid encoding ketolytic enzyme, and detecting the level of insulin resistance.

4. The inventions listed as Groups 1-30 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The invention of Group 8, the delivery vector comprising a nucleic acid encoding SCOT, has no special technical feature that defined the contribution over the prior art of Fukao et al., 2000 (of record).

Fukao et al. teach an expression vector (i.e. a delivery vehicle) that comprises a nucleic acid encoding SCOT (see page 146 in particular). Said vector would be expressed in all eukaryotic cells, including skeletal muscle cells.

5. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Accordingly, Groups 1-30 are not so linked as to form a single general inventive concept and restriction is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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